IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SMITH KLINE & FRENCH LABORATORIES, LTD, AND SMITHKLINE BEECHAM CORP., d/b/a GLAXOSMITHKLINE, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 05-197 GMS **FILED UNDER SEAL** **REDACTED – PUBLIC VERSION**

DEFENDANT TEVA PHARMACEUTICALS' REPLY BRIEF IN SUPPORT OF ITS CORRECTED MOTION FOR LEAVE TO AMEND ITS ANSWER, DEFENSES, AND COUNTERCLAIMS

John W. Shaw (No. 3362)
Monte T. Squire (No. 4764)
YOUNG CONAWAY STARGATT & TAYLOR, LLP
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, DE 19801
Telephone: (302) 571-6600
msquire@ycst.com
Attorneys for Defendant Teva Pharmaceuticals USA, Inc.

Of Counsel:
Jay P. Lefkowitz
Edward C. Donovan
Andrew B. Kay
Karen M. Robinson
Charanjit Brahma
Corey J. Manley
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Suite 1200
Washington, D.C. 20005
Telephone: (202) 879-5000

Dated: July 24, 2006

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Rules

In opposing Teva's request for leave to amend its answer, GSK asserts two arguments why this Court should deny Teva's motion for leave to raise inequitable conduct counterclaims and defenses based on recently discovered evidence. But neither argument justifies overriding the Supreme Court's directive that courts should liberally allow amendment of pleadings. That is particularly true here, where the claims at issue involve inequitable conduct against the Patent Office, the evidence regarding GSK's inequitable conduct is entirely within GSK's possession, and Teva was required to satisfy the heightened Rule 9(b) standards to plead its claims (which GSK notably does not contend to be futile).

First, Teva did not "unduly delay" raising its inequitable conduct counterclaims and defenses. GSK claims that its October 2005 response to a single interrogatory put Teva on notice of GSK's inequitable conduct. But that single interrogatory response simply does not say what GSK now claims it says, and Teva was not previously aware of the information that it recently discovered through deposition testimony. Indeed, any delay in Teva's ***discovery*** of the inequitable conduct was caused by GSK's own delay in producing relevant discovery and making witnesses available for deposition. As a result, Teva did not unduly delay raising its inequitable conduct allegations once it uncovered the relevant facts in discovery, and leave to amend should not be denied on that basis.

Second, GSK contends that allowing Teva to raise the issue of GSK's inequitable conduct at this stage would be unfairly prejudicial, because GSK would not have the opportunity to conduct fact or expert discovery to rebut Teva's evidence of inequitable conduct or to seek summary judgment on these issues. As an initial matter, this position is diametrically opposed to GSK's first argument—that GSK's own discovery responses fully supported Teva's inequitable conduct allegations long ago. But particularly since GSK's interrogatory response in fact fell far

short of disclosing the inequitable conduct now raised by Teva, GSK's complaints of unfair prejudice are not supportable. As set forth in Teva's opening brief, Teva's inequitable conduct allegations are based on the application of well-established law to the evidence that Teva has managed to uncover from GSK's ***own documents and witnesses***—a fact that undermines GSK's claim that it will be prejudiced in its ability to obtain information necessary to defend itself against Teva's claims. Finally, GSK fails to explain why any discovery prejudice it may face could not be cured in the ***five months remaining until trial.***

At this stage Teva is only asking to be allowed the opportunity to prove its inequitable conduct defenses and counterclaims to the Court at trial. The issue is not—as GSK suggests at points in its brief—whether Teva might prevail at trial. Consistent with well-established precedent, Teva should be permitted to argue its claims.

ARGUMENT

Leave to amend must "be freely given when justice so requires," Fed. R. Civ. P. 15(a), a "mandate" that must be "heeded." *Foman v. Davis*, 371 U.S. 178, 182 (1962). As cases from this District, including those cited in GSK's opposition brief, make clear, "absent a clear reason such as delay, bad faith, or prejudice, it is an abuse of discretion for a district court to deny leave to amend." *Agere Sys. Guardian Corp. v. Proxim, Inc.*, 190 F. Supp. 2d 726, 732 (D. Del. 2002) (granting leave to amend inequitable conduct defense) (cited in GSK's Opposition Brief ("GSK Opp." (D.I. 77) at 11); *see also Alvin v. Suzuki*, 227 F.3d 107, 121 (3d Cir. 2000) (refusing to grant leave to amend was abuse of discretion); *Enzo Life Scis., Inc. v. Digene Corp.*, 270 F. Supp. 2d 484, 487 (D. Del. 2003) (granting leave to assert inequitable conduct defense).

As previously discussed (Teva Opening Br. ("Teva Br.") (D.I. 74) at 12), the Supreme Court in *Foman* identified four grounds for denying leave to amend: (1) undue delay; (2) improper purpose; (3) unfair prejudice; and (4) whether the amendment would be futile.

Foman, 371 U.S. at 182. Significantly, GSK does not contend that Teva's allegations of inequitable conduct would be futile, thus ***conceding*** that the serious allegations raised by Teva would survive a motion to dismiss under both Rules 12(b)(6) and 9(b)—which is the proper inquiry under the "futility" standard. *See Alvin*, 227 F.3d at 121. Instead, GSK focuses only on Teva's alleged undue delay in raising these issues and on assertions of prejudice to GSK. To the extent GSK also attempts to confuse the issue by arguing the *merits* of Teva's inequitable conduct claims, those arguments are properly considered at trial, not on Teva's motion for leave to add these claims to the case. Based on the two *Foman* factors GSK has raised, this Court should grant Teva's motion.

I. Teva Did Not "Unduly Delay" In Seeking To Amend Its Answer.

As discussed in Teva's opening brief (Teva Br. at 13), to plead inequitable conduct, Teva was required to identify particular facts showing: (a) that information material to the patentability of a patent was withheld from the Patent Office, and (b) with the intent to deceive the Patent Office. *See Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003). Teva alleged several instances of inequitable conduct in its proposed amended complaint—four relating to the '808 patent, and two relating to the '860 patent. (Teva Br. at 17.) In opposing Teva's motion for leave to amend, GSK does not attempt to argue that it disclosed ***all*** of the facts Teva needed to plead each of Teva's six inequitable conduct allegations before the last month of fact discovery. Instead, GSK points to "examples" of facts it claims to have disclosed to Teva in a single October 2005 interrogatory response, and contends that Teva should have been "on notice" of GSK's inequitable conduct as a result. (GSK Opp. at 11-13.) As an initial matter, GSK's interrogatory response simply does not say what GSK now claims. To the contrary, the little information GSK

provided actually ***conflicted*** with the facts brought out by Teva in deposing the named inventors of the '808 and '860 patents.

In determining whether Teva "unduly delayed," the relevant inquiry is how long it took Teva to assert its inequitable conduct claims ***after*** it had discovered the necessary facts, not how long it took Teva to obtain those facts from GSK and its witnesses. *Friedl v. City of New York*, 210 F.3d 79, 88 (2d Cir. 2000) (finding no undue delay where amendment proposed only after discovery revealed additional relevant facts); *Sweetheart Plastics, Inc. v. Detroit Forming, Inc*, 743 F.2d 1039, 1044-45 (4th Cir. 1984) (holding leave to amend on day of trial appropriate where opposing party withheld relevant documents until six days earlier). And even if GSK's characterization of its interrogatory response was accurate, the isolated snippets of information that GSK claims to have disclosed to Teva in October 2005 were hardly sufficient to meet the Rule 9(b) pleading standard. Because inequitable conduct must be particularly plead under Rule 9(b), Teva "was prudent and possibly required to confirm the factual allegations through discovery" by deposing the inventors before seeking to add these defenses and counterclaims in its answer. *Enzo*, 270 F. Supp. 2d at 489 (granting leave to amend to add inequitable conduct defenses and rejecting patentee's argument that same facts were disclosed in public prosecution history). Here, Teva cannot be blamed for ***undue*** delay when GSK required Teva to depose witnesses in the last month of fact discovery, in order to obtain the facts necessary to see the big picture of GSK's inequitable conduct.

A. GSK's interrogatory response did not disclose the facts Teva recently discovered to support its inequitable conduct defenses and counterclaims.

GSK points to two portions of its response to a single Teva interrogatory as allegedly disclosing the facts Teva needed to plead its inequitable conduct defenses and counterclaims. (GSK Opp. at 6-7, 11-13.) Teva's Interrogatory No. 3 required GSK to:

> For each claim of the Patents-In-Suit, identify the alleged inventor(s) of the subject matter of the claim, and describe with particularity the facts and circumstances surrounding any alleged conception, reduction to practice, and/or claim to diligence from conception to reduction to practice, including, separately for each claim, identification of all relevant dates, locations, witnesses, documents, and things concerning such alleged conception, reduction to practice and/or diligence.

(GSK Opp. Ex. C (D.I. 78) at 4.) In response, GSK stated, through objections, that it was withholding additional relevant information about the conception and reduction to practice of the patented inventions:

> GSK objects to this interrogatory on the grounds that it is ***unduly burdensome to identify "all" relevant dates, locations, witnesses, documents, and things concerning the inventive process.*** This request is also premature to the extent that ***discovery has just begun and additional information may become available during the discovery process that relates to the questions posed in this interrogatory***.

(*Id.*, emphasis added.) GSK's substantive response with respect to the '808 and '860 patent was made "[s]ubject to and without waiving the foregoing objections." (*Id.* at 5.) The selected facts GSK chose to disclose were inaccurate (as recent discovery has proven) and/or couched in objections which made the substantive portion of GSK's interrogatory response misleading. When examined in context, it is clear that GSK's interrogatory response actually led Teva away from the evidence of inequitable conduct Teva eventually uncovered by deposing GSK's witnesses.

1. GSK misrepresented that Mr. Gallagher conceived of multiple "compounds" of the kind claimed in the '808 patent.

One of the issues raised in Teva's inequitable conduct allegations is the fact that Gregory Gallagher, the sole named inventor of the '808 patent, did not conceive of the broad invention of claim 1 of that patent, *i.e.*, a broad group of indolone compounds all lacking a 7-OH (or *para*-OH) group that exhibited cardiovascular activity. In his deposition, Mr. Gallagher admitted that, [redacted]

[redacted] And he also admitted that [redacted]

GSK now claims Teva should have known these facts from its October 2005 response to Teva's Interrogatory No. 3. (GSK Opp. at 11-12.) But that response misstated that "Gallagher ***conceived*** of the idea of removing the *para*-OH group from the aromatic ring of 4-aminoalkyl-7-hydroxy-2(3H)-indolone compound**s**." (GSK Opp. Ex. C at 5 (emphasis added).) As Teva learned at his deposition, Mr. Gallagher [redacted]

Tellingly, GSK ignores the misstatement in its interrogatory response about what Mr. Gallagher ***conceived***. Instead, GSK states that its response "made clear that Mr. Gallagher's ***reduction to practice*** of the invention claimed in the '808 patent … involved only the synthesis of ropinirole ...." (GSK Opp. at 12.) Conception and reduction to practice are distinct issues—only the former is at issue in Teva's claim that Mr. Gallagher committed inequitable conduct by falsely declaring to the Patent Office that he was the sole inventor of claims in the '808 patent covering compounds ***other than*** ropinirole. *See Perseptive Biosys., Inc. v. Pharmacia Biotech*, 225 F.3d 1315, 1324 (Fed. Cir. 2000). What GSK may or may not have said about ***reduction to***

---

[1] Exhibits A-N are attached to the July 10, 2006 Declaration of Charanjit Brahma in Support of Defendant Teva Pharmaceuticals' Corrected Motion for Leave to Amend Its Answer, Defenses, and Counterclaims (D.I. 75) and are referenced herein as "Teva Br. Ex. __".

practice in its response to Interrogatory No. 3 did not put Teva on notice of Mr. Gallagher's and GSK's inequitable conduct with respect to his representations to the Patent Office about ***conception*** of the other compounds claimed in the '808 patent.

GSK also mischaracterizes what it actually said in its October 2005 interrogatory response about reduction to practice. GSK's interrogatory response merely stated that "Gallagher synthesized ropinirole ... thereby reducing to practice the invention claimed in the patent." (GSK Opp. Ex. C at 5.) That is a far cry from saying that ropinirole was the "only" compound synthesized as part of reducing the claimed invention to practice, particularly in light of GSK's objection to producing "all" relevant facts concerning the inventive process. Specifically, until the parties' May 31, 2006 teleconference on discovery disputes, GSK objected to producing any information about compounds claimed in the asserted patents other than ropinirole, inexplicably contending that information was irrelevant. As a result, Teva could not tell from GSK's interrogatory response what, if any, other claimed compounds Mr. Gallagher may have conceived of or reduced to practice—that information came only through Mr. Gallagher's deposition in both his individual capacity and as GSK's Rule 30(b)(6) representative on "the conception and reduction to practice (if any) of the claims of the Patents-in-Suit and the development of the subject matter claimed in" the '808 patent.[2]

2. GSK's October 2005 interrogatory response did not disclose that no human testing was done on ropinirole before the '808 patent application was filed.

GSK also argues that its response to Teva's Interrogatory No. 3 put Teva on notice that "Mr. Gallagher's reduction to practice of the invention claimed in the '808 patent . . .

---

[2] GSK further delayed Teva's deposition discovery on that topic by designating Mr. Gallagher as its representative only three days before his deposition, even though Teva's Rule 30(b)(6) deposition notice had been served almost a month earlier. (Teva's First Notice of 30(b)(6) Deposition to GSK (Ex. O); 5/2/06 Ltr. from A. Wigmore to K. Robinson, Teva Br. Ex. F.)

did not involve any human testing." (GSK Opp. at 12.) But, as GSK concedes, its October 2005 interrogatory response simply "made no mention of human testing," or testing of any kind for that matter. (*Id.*) In light of GSK's refusal to disclose "all" of the relevant facts relating to the inventive process, GSK's silence as to testing could not reasonably have been read by Teva to mean that GSK performed no human testing to support the presumptively correct statement in the '808 patent that certain ranges of doses of ropinirole would "show anti-hypertensive activity" when administered to "an average size human." (Teva Br. Ex. B at col. 5, l. 67-col. 6, l. 5.) GSK cannot now reinterpret its interrogatory disclosures with the benefit of hindsight and Mr. Gallagher's deposition testimony to claim that this information was in front of Teva all along.

3. GSK's October 2005 interrogatory response did not disclose that Dr. Owen failed to conceive of using any compound other than ropinirole to treat Parkinson's disease.

All that GSK's interrogatory response said about Dr. Owen's involvement in the conception and reduction to practice of the '860 patent was that "[b]ased on tests of ropinirole conducted under his direction, Dr. Owen determined that ropinirole caused central nervous system ('CNS') activity and conceived of using ropinirole to treat central nervous system disorders including Parkinson's disease." (GSK Opp. Ex. C 5.) In its opposition, GSK irrelevantly characterizes that statement as a disclosure that "the testing commissioned by Dr. Owen concerned ropinirole, and not the other compounds covered by the '860 patent." (GSK Opp. at 7.) Regardless of what testing Dr. Owen may have asked others to do, the crux of Teva's argument is that Dr. Owen never thought that any of the compounds claimed in the '860 patent other than ropinirole could be used to treat Parkinson's.

GSK never disclosed that fact in its interrogatory response, and cannot now be heard to argue that Teva should have asserted inequitable conduct based upon information that Teva did not discover until deposing Dr. Owen. As previously noted, GSK's interrogatory

response was subject to its objection to producing "all" relevant facts concerning the inventive process. (GSK Opp. Ex. C at 5.) And until the parties' May 31 teleconference on discovery disputes, GSK refused to produce any information about compounds claimed in the asserted patents other than ropinirole. (6/2/06 Ltr. from C. Brahma to M. Gordon (Ex. P) at 3.) Thus, GSK prevented Teva from earlier discovering Dr. Owen's and GSK's inequitable conduct in naming Dr. Owen as the sole inventor of the '860 patent. Teva only discovered this information when it deposed Dr. Owen in both his individual capacity and his capacity as GSK's representative on "the conception, reduction to practice (if any) and development of the claims of the Patents-in-Suit and the development of the subject matter claimed in" the '860 patent. (Ex. O; Teva Br. Ex. F at 1.)

4. GSK's interrogatory response was misleading as to the extent of the involvement of University of Bradford researchers in the conception of the invention claimed in the'860 patent.

Finally, GSK contends that the statement in its interrogatory response that "CNS evaluations performed . . . by researchers at the University of Bradford engaged by SK&F ***further demonstrated*** ropinirole's potential as an anti-Parkinson's agent" (GSK Opp. Ex. C at 5-6 (emphasis added)), should have been enough to cause Teva to assert that the non-joinder of these researchers as co-inventors constituted inequitable conduct (GSK Opp. at 13).

First, to say that the University of Bradford researchers "***further***" demonstrated the anti-Parkinson's potential of ropinirole incorrectly implied that this concept had previously been demonstrated by Dr. Owen. To the contrary, Dr. Owen testified at his deposition that [redacted]

[redacted] *See Burroughs Wellcome Co. v. Barr Labs, Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994). [redacted]

Second, GSK's response failed to disclose that GSK did not have a single document [redacted] Considering GSK's refusal to disclose "all" of the relevant facts relating to the inventive process, GSK's failure to disclose any document corroborating Dr. Owen's conception could not reasonably have been interpreted to mean that no such document existed. When Teva learned that was the case [redacted] it promptly included that fact in its inequitable conduct allegations. For both these reasons, GSK's interrogatory response was simply insufficient to apprise Teva of the nature and import of Professor Costall's and Naylor's contribution to conception of the claimed invention, and Dr. Owen's corresponding lack of contribution.

5. GSK's Interrogatory Responses Did Not Disclose Additional Facts Supporting Teva's Inequitable Conduct Allegations.

Finally, the little substantive information GSK did provide in its October 2005 response has absolutely nothing to do with several additional facts needed to support Teva's inequitable conduct allegations. For example, GSK's response did not address:

- the ***intent*** of the inventors and other individuals involved in the prosecution of the '808 and '860 patents to deceive the Patent Office (Teva Mot. (D.I. 73) Ex. A (Proposed Am. Answer) ¶¶ 36, 42, 43, 45, 48, 50, 51, 58, 60, 62, 64, 79-82, 91, 92);

- the knowledge of particular prior art references held by individuals (*e.g.*, Paul Hieble for the '808 patent and Professors Brenda Costall and R.J. Naylor for the '860 patent) who were not, but should have been, named as inventors (*id.* ¶¶ 48, 61);

- the fact that ropinirole does exhibit tachyphylaxis, contrary to the statement in the '808 patent, and that Mr. Gallagher never verified whether ropinirole (or any of the other compounds claimed in the '808 patent) exhibited tachyphylaxis (*id.* ¶ 44, 45, 81); and

- the fact that Mr. Gallagher never conceived of an "effective" range of doses for administration to humans (*id.* ¶ 47).

GSK makes no claim that Teva was on notice of these significant facts that also support Teva's inequitable conduct claims. Because GSK does not even contend that it disclosed ***all*** of the facts Teva needed to go to the Court with its inequitable conduct claims in October 2005, it cannot argue that Teva ***unduly*** delayed discovering the facts it relies upon in asserting inequitable conduct or in seeking to raise these claims in an amended answer.

B. GSK's complaints about the timing of Teva's depositions are both irrelevant and inconsistent with the record.

GSK also mistakenly claims that Teva "unduly delayed" raising inequitable conduct issues because it took too long to depose the named inventors and individuals involved in prosecuting the asserted patents. (GSK Opp. at 14-16.)

At the outset, the record clearly shows that Teva acted promptly to depose the named inventors and other scientists whose testimony revealed GSK's inequitable conduct. GSK's remaining complaint about the timing of Teva's attempts to depose individuals involved in prosecuting the '808 and '860 patents should have no bearing on the Court's decision on whether to grant Teva's motion for leave to amend, since Teva does not cite to any evidence from these individuals in making its inequitable conduct claims.

1. Teva timely deposed the named inventors and other GSK witnesses whose testimony supports Teva's inequitable conduct allegations.

In contending that Teva should have deposed witnesses earlier in discovery, GSK ignores the fact that it withheld documents related to these witnesses until May 2006 (and in some cases, June or July 2006). As of March 15, 2006—the day Teva notified GSK that it would depose both named inventors (3/15/06 Ltr. from K. Robinson to M. Gordon, GSK Opp. Ex. E, at 1)—GSK had only produced 20,734 pages (3/14/06 Ltr. from M. Rienzi to C. Brahma, Ex. R). After additional efforts by Teva to persuade GSK to produce additional needed documents (*see, e.g.*, 3/14/06 Ltr. from K. Robinson to M. Gordon (Ex. S) at 3-5), as of May 5—the date of Mr. Gallagher's deposition—GSK had only produced an additional 6,603 pages (5/3/06 Ltr. from M. Rienzi to K. Robinson (Ex. T)), and by May 26—the date of Dr. Owen's deposition and five days before the scheduled close of fact discovery—GSK still had only produced a total of 67,226 pages (5/19/06 Ltr. from M. Rienzi to K. Robinson (Ex. U)). In contrast, in June and July, after Teva had deposed all of the witnesses cited in support of its inequitable conduct allegations and after the originally-scheduled close of fact discovery, GSK produced over 300,000 pages of documents. (*See* GSK production correspondence from 6/1/06-present (Ex. V).)

The documents GSK withheld until May 2006 or later were significant. For example, GSK waited until May 3, 2006—two days before Mr. Gallagher's deposition—to produce his laboratory notebooks.[3] (Ex. T.) And GSK did not produce any notebooks for Paul Hieble, [redacted] '808 patent and who should have been named as an inventor on that

[3] One of these notebooks had previously been served in redacted form so as to remove all mention of compounds other than ropinirole.

patent, until after the May 31, 2006 fact discovery deadline. (Ex. P at 3.) By withholding these relevant documents, GSK prevented Teva from deposing GSK's witnesses earlier in discovery. As a result, GSK should not be heard to complain about any delay by Teva, particularly since Teva still managed to depose these GSK witnesses within the originally-scheduled fact discovery period.

Moreover, when Teva did try to schedule depositions for these witnesses, GSK delayed for over a month. On March 15, 2006, Teva notified GSK that it intended to depose the named inventors and five other GSK witnesses between April 10, 2006 and May 1, 2006. (*See* GSK Opp. Ex. D at 1.) Two full weeks later, GSK responded by rejecting all of Teva's proposed deposition dates and instead proposing two deposition dates in late April and five dates throughout May, including May 26 for the deposition of Dr. Owen.[4] (*See* GSK Opp. Ex. E at 1.)

Teva's counsel accepted six of GSK's seven proposed dates. For the seventh date GSK proposed—April 21, 2006 for the deposition of Mr. Gallagher—Teva's counsel accepted the first alternate date GSK's counsel proposed—May 5, 2006.

These facts demonstrate that GSK has no basis to blame Teva for not deposing GSK's employees and retained consultants earlier in the discovery process. Had GSK promptly produced documents in discovery and made its witnesses available for deposition, Teva may have been able to discover and raise these inequitable conduct issues earlier. But GSK chose not to do so, and now GSK cannot argue that any alleged delay was "undue."

---

4 While claiming they went to "great lengths" in making witnesses available for deposition (GSK Opp. at 8, 14), GSK fails to mention that [redacted] (*See* [redacted] 3/24/06 Ltr. from A. Wigmore to K. Robinson (Ex. X).)

II. GSK Will Not Be Unfairly Prejudiced By Teva's Proposed Amendment.

Nor would GSK be "unfairly prejudiced" if Teva is permitted to pursue its inequitable conduct defenses and counterclaims. GSK's claim of prejudice cannot be reconciled with the fact that all of the documents and fact witnesses relevant to Teva's inequitable conduct defenses and counterclaims are, and always have been, ***in GSK's control***. Tellingly, GSK does not, and cannot, allege that it needs any further discovery from Teva. To the contrary, [redacted] And GSK cites no expert testimony that it could not easily obtain from its existing technical experts who presumably will opine on the validity of the same patents and have been aware of the basis for Teva's allegations for over a month. GSK has not established that it would be prejudiced by permitting Teva to pursue the inequitable conduct claims, much less that any such prejudice would be unfair in light of the circumstances. *See Minter v. Prime Equip. Co.*, No. 04-7011, -- F.3d --, 2006 WL 1775433, at *14 (10th Cir. June 29, 2006) (Ex. Y) (harm that is of a party's "own making . . . does not qualify as prejudice under Rule 15(a)"). As a result, none of the alleged "prejudices" to GSK can serve as a basis to deny Teva's request for leave to amend its answer, and Teva should not be denied the opportunity to pursue the serious matter of inequitable conduct on this basis.

Moreover, even if this Court accepted GSK's arguments that it would be prejudiced by Teva's inequitable conduct claims, any such prejudice could be cured, with the Court's permission, by extending the deadlines for discovery or submission of summary judgment motions. While GSK has shown no reason why these deadlines must be moved, if this Court concluded that GSK deserved an opportunity to conduct additional discovery or seek summary judgment on these issues, the five months left before trial would give GSK sufficient

time to proceed, and Teva would have no objection to providing a reasonable extension of the relevant deadlines, other than the trial date, to accommodate GSK's claims of prejudice.

A. GSK will suffer no prejudice from not being able to get fact discovery from their attorneys, since it cannot use such evidence anyway.

GSK mistakenly contends it will be unfairly prejudiced in its pursuit of fact discovery to rebut Teva's inequitable conduct allegations in two ways—***first,*** because it will not have testimony from William Edgerton, an attorney involved in prosecuting the '808 patent who passed away in April 2006, and ***second***, because it will not be able to obtain testimony from third party witnesses who were "involved in the prosecution of the Patents-In-Suit, aware of GSK's custom and practice in prosecuting patents in the mid 1980's, or otherwise could have knowledge relevant to Teva's allegations of inequitable conduct." (GSK Opp. at 16-17.)

As an initial matter, the fact that all of the information relevant to Teva's inequitable conduct contentions has been in GSK's control at all times undermines GSK's claim that it has been prevented from taking discovery on these issues. Indeed, GSK does not identify a single relevant, discoverable issue on which these individuals might have offered evidence to support GSK's position. For example, testimony from other witnesses[5] about GSK's "custom and practice in prosecuting patents in the mid-1980's" would be irrelevant to the specific allegations of inequitable conduct at issue here and would likely be inadmissible at trial. And

---

[5] GSK also raises the prospect of deposing Federal Circuit Judge Lourie, claiming they will need to obtain information regarding "the customary practices within GSK's patent department when the patents were prosecuted." (GSK Opp. at 2, 17, 18.) But "customary practices" are not relevant to whether GSK committed inequitable conduct in prosecuting the patents-in-suit. And Judge Lourie was not involved here—indeed, GSK did not identify Judge Lourie in either its initial disclosures or its interrogatory responses as a person with knowledge regarding the prosecution of the patents-in-suit or any other issue relevant to this case. (*See* GSK's Initial Disclosures (Ex. Z); GSK Opp. Ex. C at 4, 13.)

even if it were admissible, there is no basis to believe that GSK could not gather that evidence and present it at trial.

Moreover, GSK knew or should have known these individuals would have relevant evidence since the beginning of discovery, and could have obtained any relevant information from them months ago. Indeed, GSK identified Mr. Edgerton in its October 2005 interrogatory responses as being involved in prosecuting the '808 patent (GSK Opp. Ex. C at 4, 13), and it could have taken evidence from him months before he passed away. And in this context, GSK apparently expected that Teva would argue that the patents-in-suit were "unenforceable," *i.e.*, that the patents were procured by inequitable conduct, such that Mr. Edgerton's knowledge might be relevant. (*See, e.g.*, GSK Opp. Ex. A No. 3 ("State with particularity each and every legal and factual basis for Teva's allegations that the '808 patent is unenforceable ..."), served September 1, 2005.) Notably, after identifying Mr. Edgerton in their October 2005 interrogatory response as a person "potentially having information that bears on the present action," GSK never informed Teva that Mr. Edgerton was ill (if indeed he was, a point GSK's brief does not address) such that his testimony needed to be preserved. Only when Teva requested Mr. Edgerton's deposition did GSK inform Teva that he had passed away. Thus, it is Teva, not GSK, that is prejudiced by Mr. Edgerton's unfortunate passing.

Nor can GSK establish that any other witnesses would be able to shed more light on the conception of the patented inventions than Mr. Gallagher and Dr. Owen, GSK's Rule 30(b)(6) representatives on that topic for the '808 and '860 patents, respectively. GSK is bound by the testimony of Mr. Gallagher and Dr. Owen on these topics. *Rainey v. American Forest & Paper Ass'n, Inc.*, 26 F. Supp. 2d 82, 94 (D.D.C. 1994) ("Unless it can prove that the information

was not known or was inaccessible, a corporation cannot later proffer new or different allegations that could have been made at the time of the 30(b)(6) deposition.").

[redacted] These privileges cannot be wielded as both swords and shields. *Ampex Corp. v. Eastman Kodak Co.*, No. 04-1373, 2006 WL 1995140, at *2 (D. Del. Jul. 17, 2006) (Ex. BB) (citing *In re EchoStar Commc'ns Corp.*, 448 F.3d 1294, 1301 (Fed. Cir. 2006)) ("attorney-client privilege cannot be used as a sword and a shield."). Having prevented Teva from taking discovery on these topics for months, GSK cannot now claim prejudice for failing to offer evidence on the same topics.

B. GSK will not be prejudiced in expert discovery.

GSK also incorrectly contends that adding Teva's inequitable conduct defenses and counterclaims now will hamper its preparation of expert reports. (GSK Opp. at 17-18.) GSK makes no mention of the fact that it was fully informed about the basis for Teva's inequitable conduct allegations more than a month ago—and more than two months before GSK's expert reports on this issue are due (August 14). (Teva's 6/9/06 Third Suppl. Resps. to

GSK Interrogs. at 4-19 (Ex. CC).) Two months can hardly be called "short notice" for the preparation of expert reports.

Additionally, GSK does not provide support for its assertion that it would need to retain different experts to opine on inequitable conduct issues. The factual, technical issues associated Teva's inequitable conduct allegations relate to the same field as the factual, technical issues related to Teva's invalidity defenses, which have been in the case since Teva first filed its Answer. Accordingly, Teva relied upon the same experts to opine on technical issues related to validity and inequitable conduct. There is no reason why GSK cannot do the same.

Finally, GSK cannot complain that its experts may "hav[e] to provide reports and testimony without the benefit of all the facts related to these claims," (GSK Opp. at 18) when all of the information and witnesses relating to GSK's inequitable conduct have been in GSK's control. Accordingly, GSK has not shown that it will face any real prejudice in expert discovery.

C. GSK is not unfairly prejudiced by the passage of the deadline for summary judgment motions.

Lastly, GSK mistakenly argues that adding Teva's inequitable conduct allegations to this case now would be prejudicial because GSK would be "deprived of the right to seek summary dismissal of some or all of the new claims." (GSK Opp. at 18.) But, GSK has already conceded that Teva's inequitable conduct allegations are not futile, or else it would have raised that futility as a basis for denying Teva's instant motion. In any case, to the extent GSK's ability to seek summary judgment is implicated here, this alone should not be enough to deprive Teva of the ability to assert serious claims of inequitable conduct against the Patent Office; at most, it is reason to allow GSK to seek summary judgment within the five months remaining before trial.

On its merits, GSK's assertion that it could defeat Teva's inequitable conduct claims on summary judgment appears to be based on its misinterpretation of the "intent to

deceive"[6] element of an inequitable conduct claim—an "inherently factual" issue.[7] *See Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1317 (Fed. Cir. 2006) (citing *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997) (explaining that summary judgment on inequitable conduct "relate[s] to the inherently factual nature of the issue of intent"). As the Federal Circuit has acknowledged, "[d]irect evidence of intent is rare" and, in the context of any summary judgment motion GSK might have brought, the circumstantial evidence Teva presented in its opening brief (Teva Br. at 5-12) would support an inference of intent. *See Digital Control*, 437 F.3d at 1317. While GSK takes issue with what Teva has supposedly not shown—*i.e.*, the identity of an unjoined inventor[8] and a motive to deceive the Patent Office[9]—none of these things is required to prove inequitable conduct. Accordingly, even if inequitable conduct were considered appropriate at the summary judgment stage, GSK would have been unlikely to succeed on such a motion.

Because the intent to deceive prong of inequitable conduct is an inherently factual issue and intent is typically inferred from circumstantial evidence like that identified by Teva,

---

6 GSK's argument that Teva has not demonstrated intent to deceive is premature. At this stage, where Teva only seeks leave to raise its inequitable conduct claims, Teva is under no burden to present evidence. Rather, Teva is only required to show—and has shown—that its proposed inequitable conduct counterclaims and defenses "state a claim upon which relief could be granted." *Alvin v. Suzuki*, 227 F.3d 107, 121 (3d Cir. 2000).

7 GSK notably makes no argument that Teva's allegations fall short as to the other prong of inequitable conduct—materiality.

8 Teva particularly should not be required to plead the identity of a unnamed co-inventor where the patents' named inventor and GSK's Rule 30(b)(6) representatives on conception of the inventions of the '808 patent could not tell who conceived the broad claimed inventions. (Gallagher Dep. Tr. at 90:6-91:11 (cited at GSK Opp. at 23).)

9 Contrary to GSK's assertion, Teva has already alleged, for example, that J. Paul Hieble was not joined as an inventor on the '808 patent and Professors Naylor and Costall were not joined as inventors on the '860 patent in order to avoid disclosing material prior art these individuals were aware of to the Patent Office. (Am. Answer ¶¶ 48, 61.)

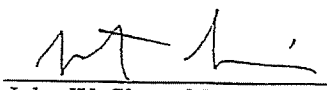
Teva's claims would not have been susceptible to dismissal on summary judgment. Thus, if Teva's motion is granted, GSK will not be unfairly prejudiced in this respect either.[10]

CONCLUSION

For the foregoing reasons, and the reasons stated in Teva's corrected motion and corrected brief, Teva respectfully requests that this Court grant Teva's Corrected Motion to Amend its Answer, Defenses, and Counterclaims.

Dated: July 24, 2006

Respectfully submitted,



John W. Shaw (No. 3362)
Monte T. Squire (No. 4764)
YOUNG CONAWAY STARGATT & TAYLOR, LLP
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, DE 19801
Telephone: (302) 571-6600
msquire@ycst.com
Attorneys for Defendant Teva Pharmaceuticals USA, Inc.

Of Counsel:
Jay P. Lefkowitz
Edward C. Donovan
Andrew B. Kay
Karen M. Robinson
Charanjit Brahma
Corey J. Manley
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Suite 1200
Washington, D.C. 20005
Telephone: (202) 879-5000

10 GSK devotes a substantial portion of their brief to arguing the merits of Teva's proposed inequitable conduct claims and defenses. Because the motion at issue is one for leave to amend, and not for summary judgment, such argument is improper.

CERTIFICATE OF SERVICE

I, Monté T. Squire, Esquire, hereby certify that on July 31, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

Patricia Smink Rogowski, Esquire
Connolly, Bove, Lodge & Hutz LLP
The Nemours Building
1007 North Orange Street
Wilmington, DE 19801

I further certify that on July 31, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and the following non-registered participant in the manner indicated:

BY E-MAIL AND FEDERAL EXPRESS

William F. Lee, Esquire
Wilmer, Cutler, Pickering, Hale and Dorr LLP
60 State Street
Boston, MA 02109

Michael E. Gordon, Esquire
Wilmer, Cutler, Pickering, Hale and Dorr LLP
1875 Pennsylvania Avenue, N.W.
Washington, DC 20006

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Monté T. Squire
John W. Shaw (No. 3362)
Monté T. Squire (No. 4764)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
(302) 571-6600
msquire@ycst.com
Attorneys for Teva Pharmaceuticals U.S.A., Inc.